K012753

NOV 1 3 2001

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
August 2, 2001

Submitter's Information:
Soring GmbH Medizintechnik
Justus-v.Liebig 10
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Trade Name, Common Name, Classification:

Trade Name:	Sonoca 190, Sonoca 180
Common Name:	Instrument, Ultrasonic Surgical
Classification Name:	General & Plastic Surgery

Predicate Device:

Applicant:	Söring GmbH
510(k) Number:	K992026
Device:	Sonoca 300

Device Description:
SONOCA 180 & 190 is a desktop unit that controls ultrasonic handpieces used in general surgery, vascular surgery, and dermatological surgery.
The device is a stand-alone unit in a compact case; technologically derived from the Sonoca 300 family of units (K992026) with the same general modules (hardware and software).

During the use of this ultrasonic dissector, power is transmitted from a longitudinal vibrating probe tip in the contact zone to tissue and is a supplementary tool for the selective dissection of human tissue.

Indications for Use:
The SONOCA 180/190 is an instrument intended for selected ultrasound dissection and fragmenting of tissue at the operation site during multi-medical discipline surgery including: General Surgery, Neuro, Thoracic, Urology, and Gastro-intestinal modalities.

Typical users of this system are trained professionals; physicians, nurses, and technicians.

Performance Data:

The subject and predicate devices both use similar software controls to detect errors. The subject device complies with IEC 950 – Safety of Information Technology Equipment, CISPR 22, class A – Electromagnetic Compatibility, IEC-801-2, IEC-801-3 – Electromagnetic Compatibility, IEEE 1003.1 – General Electrical Safety for medical devices, IEC 601-1 –Electrical Safety for medical devices using RF-power, IEC 601-2-2 – Ultrasonic surgical devices, DIN EN 61847

Conclusion:

Similar to the predicate device, the Sonoca 180/190 does not control any life sustaining functions or services. The device and the predicate device share the same conformance to performance standards and both function as Ultrasonic Dissectors. Based on the information supplied in this 510(k), we conclude that the subject device is safe, effective, and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2001

Soring GmbH Medizintechnik
c/o Mr. Carl Alletto
1100 Lakeview Boulevard
Denton, Texas 76208

Re: K012753
Trade/Device Name: Soring GmbH, Sonoca 180/190
Regulation Name: Ultrasonic surgical instrument
Regulatory Class: Unclassified
Product Code: LFL
Dated: July 30, 2001
Received: August 16, 2001

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012753

NOV 1 3 2001

(Indications for Use Form)

510(k) Number: K012753

Device Name:
Soring GmbH, SONOCA 180/190

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milkins

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012753